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Cantu, Paolo

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Review Article

Covered metal stents in endoscopic therapy of biliary complications after liver transplantation

Paolo Cantù [a], Andrea Tenca [b], Ilaria Parzanese [a], Roberto Penagini [a,*]

[a] Gastroenterology and Endoscopy Unit, Department of Pathophysiology and Transplantation, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico and Università degli Studi di Milano, Milan, Italy
[b] Clinic of Gastroenterology, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

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ABSTRACT

There is growing interest in using covered self-expandable metal stents for the treatment of benign biliary conditions, and the presence of anastomotic biliary strictures and leaks after liver transplantation provide a valuable opportunity for testing them. The performance of the stents is encouraging, and the technical success rate is high. They provide larger diameter dilation and are easily removed, and can potentially limit costs by reducing the number of procedures needed to treat anastomotic biliary strictures. However, drawbacks such as sub-optimal tolerability and migration may affect both patient management and costs. New stent designs are currently being evaluated. Randomized controlled trials and cost-effectiveness analyses comparing covered metal stents with multiple plastic stent endotherapy are warranted in order to define the role of the former as first-line or rescue treatment.

1. Introduction

Biliary complications after orthotopic and living donor liver transplantation (LT), of which biliary strictures and leaks are the most common, still play a major role in graft dysfunction and re-transplantation [1], and endoscopic retrograde cholangiopancreatography (ERCP) is currently considered the reference standard for their treatment. In patients with a Roux-en-Y anastomosis, endoscopic therapy using dedicated devices should first be used [2], and percutaneous or surgical options should only be considered in the case of failure [3].

Endoscopic treatment is traditionally based on the use of plastic stents with or without balloon dilation but plastic stenting has two main limitations: more than one stent (*i.e.* multiple stenting, MPS) is frequently required to treat anastomotic strictures (AS) in order to optimize dilation at the anastomotic site [4], and as consequence of their tendency to clog within three months they therefore need to be replaced [4]. The recently approved and commercially covered self-expandable metallic stents (CSEMSs) are made using metal mesh technology in order to obtain a larger diameter and a plastic cover that prevents ingrowth and facilitates stent removal, and may therefore lead to longer patency [5]. Although the optimal strategy has not yet been defined, CSEMSs may reduce the need for procedures and therefore costs of treating post-LT biliary complications. Interest in this issue is confirmed by the increasing number of papers reporting their use.

The aim of this review is to describe the published outcomes of CSEMS treatment and its main differences from traditional endotherapy using plastic stents. The summarized data were obtained from articles identified by means of a PUBMED search carried out in February 2015. No restriction of publication data for original manuscript or reviews was used. The keywords "covered biliary stent", "anastomotic biliary stricture", "liver transplantation" and "ERCP", "biliary stent" and "bleeding" and "biliary stent and leak" were considered. Studies centred on paediatric series ($n=1$), percutaneous approach ($n=2$) or non-English language ($n=2$) were excluded. Revisions of 131 original articles and 11 reviews or commentaries were performed by the authors. When data regarding LT transplants could not be extrapolated from the articles themselves, the authors were contacted by e-mail. Fifty-five papers were finally included as relevant ones in the present review.

2. Post-liver transplantation biliary complications

Biliary complications still cause morbidity and mortality in 8–35% of transplanted patients [6]. The most common are

* Corresponding author at: Gastroenterology and Endoscopy Unit, Department of Pathophysiology and Transplantation, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Università degli Studi di Milano, via F. Sforza 35, 20122 Milano, Italy. Tel.: +39 02 55033311; fax: +39 02 50320403.
E-mail address: roberto.penagini@unimi.it (R. Penagini).

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biliary strictures (5–15% of orthotopic and 28–32% of living donor LT), biliary leaks (2–25% of patients), and sphincter of Oddi dysfunction (7%), followed more rarely by biliary stones, casts, biloma and hemobilia [1]. Strictures may be anastomotic (AS) or non-anastomotic (NAS) with widespread involvement of the intrahepatic biliary tree, but both usually have a similar clinical presentation characterized by fever, jaundice, abdominal pain or asympotomatic cholestasis. Endoscopy is considered the treatment of choice for AS because of its high success rate, whereas a percutaneous approach or re-transplantation is needed for NAS after endoscopic failure [7,8].

Leaks at the site of the anastomosis and T-tube insertion can be caused by surgical damage or local ischemia, and sustained by obstruction due to stones, casts or sphincter of Oddi dysfunction. In the presence of suggestive symptoms or signs such as cholestasis, cholangitis, bilious ascites or peritonitis, the diagnosis is confirmed by means of non-invasive cholangiography and ERCP [9]. Endoscopic treatment is usually highly effective, but surgery is needed in the few cases of endotherapeutic failure [9].

Sphincter of Oddi dysfunction is thought to be due to biliary denervation of the native common bile duct, and is suspected in patients with cholestasis and dilated bile ducts in the absence of other conditions leading to biliary obstruction. There is no consensus concerning therapy of sphincter of Oddi dysfunction. Other obstructive conditions (biliary stones, sludge and casts) and hemobilia has been found to be successfully treated as in non-LT patients [6].

3. CSEMS and anastomotic biliary strictures

Traditionally multiple plastic stenting (MPS), *i.e.* the insertion of a progressively increasing number of plastic stents every three months for one year, has been considered the therapy of choice for benign biliary strictures (BBSs) [10] and, more recently, in LT patients. Published resolution rates range from 30% to 100% [11], a variability that may be due to differences in patient selection and endotherapy. The placement of a single plastic stent for one month may be helpful in selecting clinically relevant AS in LT patients with multiple factors leading to symptoms and/or high liver enzyme levels [12]. Short-term MPS (up to 6 months) has also been proposed [13], but a late AS probably needs a longer time to respond [14,15]. An approach based on stent exchange on demand (when symptoms or signs of biliary are detected) has been also proposed [11]. There are conflicting data concerning living donor LT: some studies have found the same stricture resolution rate as in the case of orthotopic LT [16], but others indicate a less favourable response [17].

The use of CSEMS has been proposed as an alternative means of treating AS after LT with a reported efficacy of 53–100% (Table 1 and Fig. 1) [9,18–24]. Interestingly, this wide range may be biased by different factors, such as the heterogeneity among the studies especially regarding the definition of AS, the primary therapy performed, the duration of treatment and follow-up.

No large randomized controlled trial comparing MPS and CSEMS outcomes has yet been conducted, and so the efficacy data generally comes from prospective/retrospective observational series, including patients with strictures of non-LT etiologies (*i.e.* chronic pancreatitis, stones, other surgery) (Table 1) [25–27].

CSEMS may have several advantages. First of all, the placement is easy and fast as suggested by the high technical success rate reported, which is comprised between 86 and 100% among studies [18,22]. Secondly, a single CSEMS may provide a higher radial force at the anastomotic site when compared with MPS resulting in a longer patency [18,28]. These benefits may have an impact also on the costs of the endoscopic treatment, reducing hospitalization

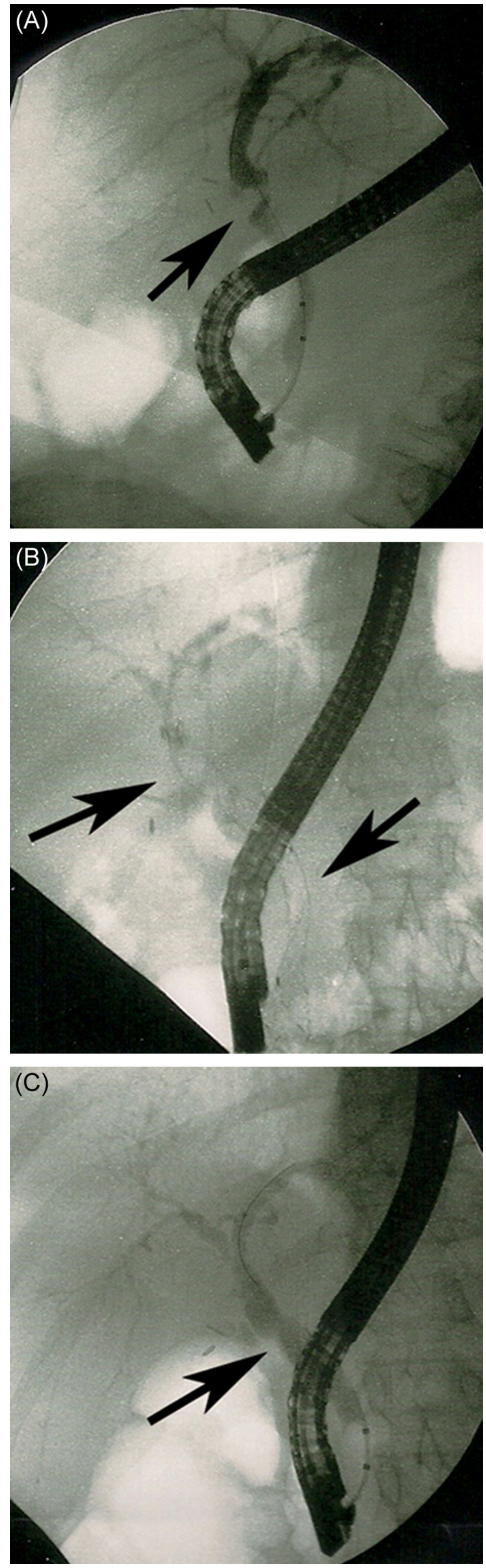

Fig. 1. (A) Anastomotic biliary stricture confirmed by means of ERCP (black arrow). A 10 cm long and 10 mm wide CSEMS was placed through the stricture (B) and removed six months later. (C) The radiological success of the endotherapy was assessed by means of cholangiography (black arrow).

Table 1
Studies of the efficacy of CSEMS in treating AS after LT.

Authors	Design	Pts with AS	Primary therapy	Stent	Clinical success No. (%)	Rescue therapy No. (%)	Complications No. (%)
Vandenbroucke et al., 2006 [18]	Retrospective single-centre study	21	No	Wallstent Fully covered Duration: NS	15/21 (66%)	Surgery: 5 (24%) Re-LT: 2 (10%)	Pancreatitis: 3 (14%) Cholangitis: 2 (9%) Areoportia: 1 (5%)
Kahaleh et al., 2008[a] [25]	Prospective single-centre study	16	Yes	Wallstent Partially covered Median duration: 4 months	15/16 (94%)	NS for AS	NS for AS
Traina et al., 2009 [9]	Prospective single-centre study	16	No	Taewong Fully covered Duration: 2 months	14/16 (87%)	NS	Migrations: 6 (37%)
Mahajan et al., 2009[a] [26]	Prospective single-centre study	9	No	Viabil Fully covered Duration: 3 months	NS for AS	NS for AS	NS for AS
Chaput et al., 2010 [19]	Prospective multi-centre study	22	No	Wallstent Partially covered Duration: 2 months	19/22 (86%)	MPS: 2 (18%) CSEMS: 1 (4%)	Pancreatitis: 3 (14%) Pain: 1 (4%) Cholangitis: 1 (4%) Migrations: 3 (14%) Embedding: 6 (27%)
Garcia-Pajares et al., 2010 [20]	Retrospective single-centre study	22	No	Unknown	21/22 (95%)	CSEMS: 1 (4%)	Pain: 4 (18%) Migrations: 5 (23%) Obstruction: 3 (14%) Embedding: 1 (4%)
Hu et al., 2011 [21]	Prospective single-centre study	13	Yes	New stent Fully covered Duration: 3–6 months	12/13 (92%)	1 patient: NS	Pancreatitis: 1 (8%)
Tarantino et al., 2012 [22]	Prospective multi-centre study	15 39	No Yes	Taewong Fully covered Duration: 2 months	8/15 (53%) 28/39 (72%)	NS	None
Haapamaki et al., 2012 [24]	Retrospective single-centre study	17	Yes	Allium, Micro-Tech, Wallstent Fully covered Duration: 3–4 months	17/17 (100%)	CSEMS: 5 (29%)	Migration: 5 (23%) Pancreatitis: 1 (6%) Cholangitis: 5 (23%) Bleeding: 1 (6%)
Poley et al., 2012[a] [27]	Prospective single-centre study	6	No	Hanaro Fully covered Duration: 5–8 months	NS	NS	NS
Sauer et al., 2012 [23]	Prospective single-centre study	8	No	Wallflex Fully-covered Duration: 12 months	5/8 (63%)	CSEMS: 1 (13%)	NS for AS

CSEMS: covered self-expandable metal stent; AS: anastomotic stricture; LT: liver transplantation; MPS: multi-plastic stenting; NS: not stated.
[a] Studies including patients with benign biliary strictures, but data regarding AS are difficult to extrapolate.
In this study, CSEMS were used as first-line ($n = 15$) and second-line therapy ($n = 39$).

and endoscopic sessions; however, there are few published data in this regard [29]. In the randomized trial conducted by Kaffes et al. CSEMS and MPS treatment have been compared, showing a low number of endoscopic procedure in the first arm to obtain a similar stricture resolution rate. CSEMS group had also a low number of complications. These results made the use of CSEMS cost-effective with a save of about 12.000$ per patient [29].

The efficacy of CSEMS as first- *vs* second-line therapy is still unclear. Tarantino et al. reported a higher success rate in patients treated with CSEMS after MPS failure (72% *vs* 53% respectively) [22], but a recent a systematic review of 10 studies found that stricture resolution rates were similar (82% *vs* 78%) [30]. There is also no agreement concerning the best strategy in the case of CSEMS failure as some authors propose switching to MPS and others retreatment with CSEMS (Table 1). Furthermore, the impact of the duration of stenting on the stricture resolution rate is still debated: in the majority of early studies, CSEMS were placed for 2–4 months [9,19,22–24], and some authors recommended not leaving the stent in place for more than six months in order to reduce retrieval difficulty and complications such as late migration or secondary strictures [19,21,25]. However, a short period of stenting may have a negative effect on stricture resolution and recurrences, and continuing improvements in stent design led to consider safe to leave a CSEMS in place for at least six months: in this regard, the same systematic review showed that the stricture resolution rate was higher in patients stented for >3 months than in those stented for <3 months (89% *vs* 72%), thus highlighting the impact of the duration of treatment [30].

The known complications of CSEMS are mild (Table 1). Abdominal pain soon after stent placement is reported by to 18% of LT patients and 56% of BBS patients, but it usually responds to analgesic drugs and does not require stent removal [20,27]. Both proximal and distal migration was once frequent [25], but this complication has been overcome by improving the design of the stents and their anchoring systems (see below). Pancreatitis has been reported in up to 14% in some studies but it was usually mild [18,19]. Although sphincterotomy could be avoided with CSEMS, this is usually done in order to prevent the obstruction of the pancreatic duct and consequently pancreatitis [21,24]. Cholangitis has been reported in about 10% of patients, probably as a consequence of a partial hilar obstruction or the use of an over-sized stent [18]. Bleeding is usually rare and self-limiting, although a higher rate of bleeding after sphincterotomy in LT patients has been reported [31].

Percutaneous or surgical approaches are usually reserved for cases of endoscopic failure [18]. A second AS after CSEMS has occurred in up to 47% of patients [19,22], but subsequent treatment has varied widely (repeat MPS or CSEMS, or percutaneous and/or surgical interventions) [9,19].

The plastic stenting of a NAS after LT is a challenge. The presence of multiple intrahepatic or hilar strictures limits the success of endoscopic therapy, and most cases require a percutaneous intervention, surgery or re-LT [7,8].

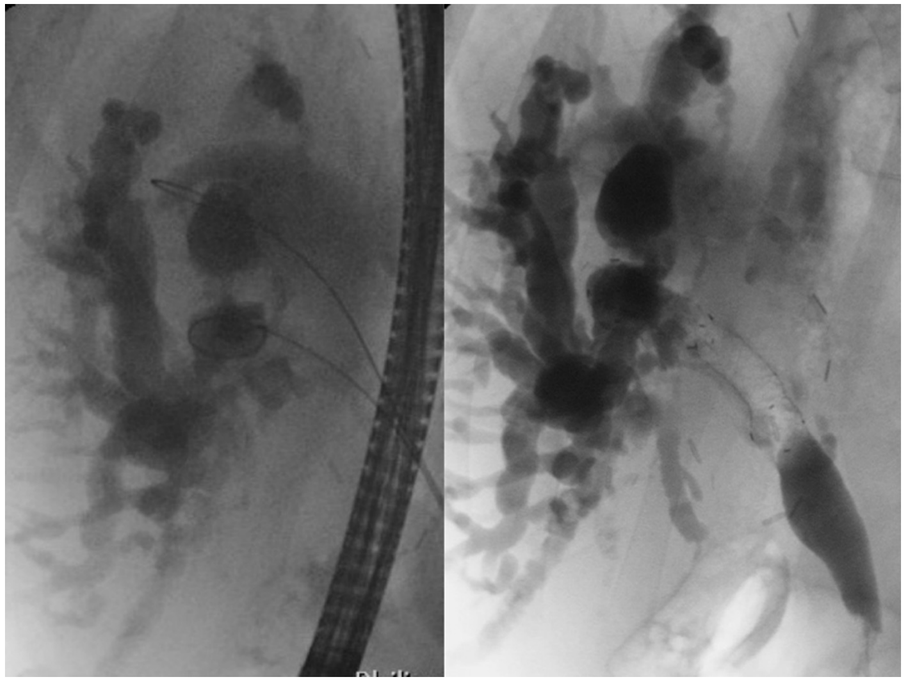

Fig. 2. Leak with an associated biloma confirmed by means of ERCP. On the left, one guide-wire was placed inside the biloma and another in the right intra-hepatic duct. On the right, sphincterotomy was performed in order to reduce trans-papillary pressure before the placement of a suspended CSEMS.
From Helsinki University Central Hospital, Abdominal Centre, Gastrointestinal Surgery, Helsinki, Finland.

Although the use of CSEMSs is contraindicated by some authors, a few cases during PTC have been reported mostly in patients with living-donor LT [9,18].

4. CSEMS and leaks

CSEMS have become increasingly used for treatment of post-surgical biliary leaks in non-LT patients after failure traditional plastic stenting [32–34]. The aim of endotherapy is to reduce the transpapillary pressure gradient between the biliary tree and the duodenum by means of a stent with or without sphincterotomy (Fig. 2) [35,36], an approach that is highly successful (>90%) in the case of minor leaks, although major leaks still require hepato-jejunostomy in both LT and non-LT patients. CSEMS were initially proposed as rescue therapy for leaks refractory to conventional treatment because of their larger diameter, long-term patency and removability [9,33,37–39].

There is still a lack of randomized controlled studies comparing CSEMS and plastic stents in terms of isolated bile leaks. Most published studies consider the endoscopic treatment of bile leaks associated with AS after LT, for which dilation and MPS are usually used.

Traina et al. reported a high success rate of CSEMS (87.5%) in treating bile leaks associated to AS in a short series of patients refractory to standard endoscopic therapy. As asymptomatic stent migration occurred in six cases without need of retreatment the leak, authors suggested that dilation of AS by CSEMS could favour stent dislocation. Only one LT patient (double biliary anastomoses) showed AS recurrence after ten months of follow-up from CSEMS removal, which was treated by means of percutaneous trans-hepatic drainage [9]. A smaller series of three LT patients with anastomotic leak associated to AS refractory to plastic stent were successfully treated with CSEMS, showing a relevant prevalence of post-insertional pain (18%) and migration (22%) in the overall study population of 22 LT patients with biliary complications. After one year of follow-up, one patient experienced a stricture recurrence, which was treated by a second CSEMS [20]. It is expected that the rate of complications when using CSEMS to treat bile leaks associated with AS (migration and pain) will be similar to that observed in LT patients with AS alone.

A pilot study of 17 patients with bile leaks after LT (associated with AS in five cases) treated with fully CSEMS as first-line treatment for a median of 102 days reported optimal leak healing. However, there was a considerable rate of secondary strictures (47%) after stent removal, most of which were successfully managed using plastic stent, and a second fully CSEMS was used only in one case [40].

There are few studies of LT patients affected by leaks without AS. In the largest of these studies [37], 31 LT patients with major leaks (22 anastomotic and nine non-anastomotic) not responding to plastic stenting ($n = 8$) or with comorbidities contraindicating multiple procedures ($n = 23$) were managed by placing different fully ($n = 28$) or partially CSEMS ($n = 3$), which were removed within four months. The success rates >6 months after stent removal ranged from 70 to 100%, but secondary strictures occurred in up to 33% of the patients receiving partially CSEMS, 35% of those receiving a fully CSEMS with fins, and 10% of those receiving a fully CSEMS with flared ends. Tissue ingrowth at the level of the proximal metal meshes was assessed by cholangioscopy. Minor complications were cholangitis (5.6%) and stent migration (5.6%) [37]. However, the use of fully CSEMS has now become more favoured than partially CSEMS to reduce ingrowth at uncovered sites and facilitate removal.

Unexpectedly, the main challenge when using a CSEMS to treat isolated leaks is not migration but secondary strictures. Frequently asymptomatic distal migration of a fully CSEMS has only been reported in 8% of cases and not required retreatment, whereas strictures secondary to CSEMS treatment have been observed overall in 27% of patients [37,39], although they can be successfully managed by means of repeat endoscopic treatment (MPS or CSEMS).

In order to define the role of CSEMS in treating leaks after LT, there is a need for randomized studies comparing plastic stents with CSEMS in previously untreated patients and those experiencing recurrences after traditional endotherapy.

Table 2
Studies of marketed SEMSs or prototypes tested for AS treatment in LT patients, in chronological order of publication.

Name	Brand	Covering type	Anti-migration system	Removal system	No. of patients	Migration (%)	Removal complications (%)	References
Wallstent	Boston Scientific (USA)	Partially permalume	Uncovered ends	Distal loop	74	0–10	0–9	[18,19,25,52]
Niti-S Com Vi	Taewoong Medical (Korea)	Fully PTFE	Flared ends	Distal loop	55	37	0	[9,22]
GoRe Viabil	Conmed (USA)	Fully PTFE/FEP	Proximal fins	–	30	0	0	[26,52]
WallFlex	Boston Scientific (USA)	Fully permalume	Flared ends	Distal loop	86	0–55	0–28	[23,36,38,39,43,51,52,55]
Prototype	M.I. Tech (Korea)	Fully silicone	Reversed cone shape	Log distal lasso	43	0–10	0	[21,49]
Bonastent	Standard Sci-Tech Inc (Korea)	Fully silicone	Flared ends	Distal loop	2	NS	NS	[46]
Hanarostent	M.I. Tech (Korea)	Fully silicone	4 (anchoring) proximal flared flaps	Proximal and distal lassos	7	0	0	[27,50]
Bonastent M-intraductal	Standard Sci-Tech Inc (Korea)	Fully silicone	Waisted	Distal loop	3	NS	0	[47]
Niti-S Kaffes prototype	Taewoong Medical (Korea)	Fully PTFE	Waisted	Long distal string	10	0	0	[29]

SEMS: self-expandable metal stent; LT: liver transplantation; AS: anastomotic stricture; PTFE: polytetrafluoroethylene; FEP: fluorinated ethylene propylene; NS: not stated.

5. CSEMS and rare biliary complications

Covered SEMSs have recently been used to treat other benign conditions such as bleeding unresponsive to usual therapies (epinephrine injection, argon plasma coagulation or clip) [41–43] and portal hypertensive biliopathy [44,45]. The success rates are optimal and no complications have occurred after removal within a few weeks. CSEMS has also been used to treat perforations secondary to sphyncterotomy or ampullary adenoma resection in a small number of patients [43]. No cases of refractory bleeding or perforations in LT patients have yet been published, but this therapeutic option could be considered after the failure of standard treatments if a CSEMS is readily available.

6. Commercially available CSEMS in LT patients

CSEMS were originally designed to treat malignant biliary strictures, but their use subsequently extended to biliary strictures in general, and the number of commercially available models has continued to increase (Table 2) [9,18,26,27,29,39,46,47].

Randomized studies comparing covered and uncovered SEMS did not find any difference in terms of patency rates in patients with malignant biliary strictures [48], but they have a short life expectancy by definition.

Most CSESMs are designed to be placed across the papilla, whereas others were developed to be suspended inside the common bile duct in order to treat short strictures; both have shown promising performances in LT patients [29,47,49].

Silicone, permalume or polytetrafluoroethylene (PTFE) membranes covers prevent ingrowth through the metal meshes, thus facilitating stent removability. However, the time of removal ranges from four to >12 months depending on the brand, and particular removal systems are required to facilitate stent capture and extraction (Table 2). Rat-tooth forceps are used to grasp distal lasso, string or loop firmly, and forceps retrieval stretches the metal meshes and allows easy removal through the accessory channel or by withdrawing the duodenoscope. Removal has been successful in almost all attempted cases and there are only anecdotal reports of impaction. One CSEMS model has a double removal system consisting of a proximal and distal lasso [27,50], and passing an inflated balloon catheter inside the stent can expose them when they are not visible among the debris. In case of difficult removal, grasping and retrieving the proximal lasso allows the inversion of the proximal end into the duodenum and aids removal. An alternative technique is to use a snare to grasp the duodenal end. In the case of proximal migration, grasping the distal meshes with rat-tooth forceps under X-ray guidance been found to be successful. Retrieval is more difficult when overgrowth arises at the impacted intrabiliary distal end of a CSEMS. The reported complications include cholangitis (0–4%) [43], pancreatitis (0–18%) [39], and transient hemobilia (0–4%) [19,51] due to local trauma, all treated conservatively.

Plastic covers facilitate removal but also spontaneous migration, which occurs in up to 55% of cases [9,36,39] and have encouraged the development of anti-migration systems. The addition of proximal anchoring flaps [27,50] or multiple fins [52] has reduced migration rates but can give rise to ulcerations of the biliary wall secondary to mechanical trauma, and lead to strictures that can be seen by means of cholangioscopy after CSEMS removal [53]. However, no randomized controlled trials comparing different CSEMSs have yet been published because of the large LT population needed.

Available lengths of CSEMS range from 4 to 12 cm [5,54]. Considering anatomical change of extrahepatic biliary duct after LT, the most used CSEMSs are 8 and 10 cm long. When deciding on the appropriate length, it is necessary to balance post-release shortening (up to 40%) and CSEMS-induced straightening of peri-anastomotic angulation. The available diameters range from 6 to 10 mm [5] according to the calibre of the extrahepatic biliary duct. A small diameter CSEMS may migrate, whereas one that over-large may theoretically be less tolerable and lead to abdominal pain during the expansion of the metal mesh, and later strictures due to biliary damage.

Some authors consider avoiding biliary sphincterotomy a possible means of minimizing the risk of migration, but sphincterotomy is currently used in everyday clinical practice in order to facilitate stent placement and possibly reduce the incidence of post-ERCP pancreatitis [55]. Nowadays CSEMS with an enteroscopy dedicated delivery system are not yet commercially available. Dedicated CSEMS models are waited in parallel with increasing use of enteroscopy in this field.

Finally, the choice of a CSEMS should be tailored on the basis of a balance between costs and technical considerations in order to optimize their efficacy and efficiency.

7. Conclusions

The use of CSEMS in LT patients is increasing, but there is currently no optimal design that simultaneously ensures a high success rate, easy removability and minimal migration. However, the many designs available on the market allow tailored endotherapy. Randomized controlled trials comparing the use of CSEMS and traditional MPS are currently ongoing with the aim of defining the role of CSEMS as first- or second-line treatment (after MPS) for AS, but there is still a need for controlled tolerability evaluations and cost analyses, as well as appropriately sized comparative studies of CSEMS with different designs.

Conflict of interest

None declared.

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